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SENSITIVE
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SUBJECT: SFDA'S TREATMENT OF BAXTER IN CHINA

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¶1. (SBU) SUMMARY: Representatives of Baxter Healthcare (protect) visited the U.S. Embassy in Beijing to present their concerns about the deterioration of relations with China's State Food and Drug Administration (SFDA) amid concerns that the agency may try to shift responsibility for the heparin problem away from China, to the detriment of Baxter. END SUMMARY

UNANNOUNCED INSPECTIONS

¶2. (SBU) On May 27, three representatives of Baxter Healthcare, including Stanley Lau (protect), the General Manager for Baxter in China, Marie Kissel (protect), the Regional Director for Government Affairs, and Charles Chen (protect), an Assistant General Counsel, visited the U.S. Embassy in Beijing to brief HHS Health Attache and Econoff. The company presented concerns about the deterioration of relations with China's State Food and Drug Administration (SFDA) and the possibility that the SFDA may be looking to retaliate for perceived uncooperative behavior when SFDA staff visited the company's Cherry Hill facility in April. COMMENT: This SFDA visit, to the facility where Baxter's recalled heparin sodium U.S.P. was manufactured, followed the April 17-18 International Regulators Meeting on Heparin in Washington DC sponsored by the U.S. Food and Drug Administration (FDA) which gathered heparin experts and representatives from 12 different drug-regulating authorities to discuss the ongoing heparin investigation and its methodology. END COMMENT.

¶3. (SBU) General Manager Stanley Lau stated that Baxter's plant in Guangzhou has been investigated twice in recent weeks by two separate SFDA ''flying-squad'' teams. Unlike previous visits, when the local FDA had been notified and informed of a pending inspection, the SFDA inspectors arrived unannounced and without informing the local FDA about the inspection. The manner and tone of the investigators was aggressive and the inspectors

seemed not to listen to any of the explanations offered by the facility managers. The first investigation yielded a laundry list of 20 problems at the facility and the second cited five problems (3 as being critical and 2 listed as major).

SFDA APPEARS TO CUT OFF COMMUNICATION

¶4. (SBU) Stanley Lau stated that relations with SFDA were positive until a small SFDA group traveled to the Baxter plant in Cherry Hill, New Jersey in April 2008. In traveling to the U.S. to attend the International Regulators Meeting on Heparin, the SFDA team had hoped to gain some insight into downstream segments of the heparin market. The SFDA requested the Cherry Hill plant visit in an informal late night call placed to Baxter, and the FDA learned a few days in advance of the proposed visit when Baxter called to discuss it with them. SFDA officials attending the FDA-sponsored International Regulators meeting on heparin were informed by the FDA in advance that they would not have the legal right to demand drug production samples (as the product was neither sold in China nor regulated by SFDA). During the SFDA visit, Baxter expressed its preference to provide samples through official USG channels. When SFDA was not able to obtain heparin samples on site, relations appeared to sour. NOTE: During the recent

February FDA inspection at Baxter's affiliated plant, Changzhou SPL, where SFDA was an observer, FDA investigators asked and received samples of specifically requested production lots held at the plant. The SFDA similarly requested and later received samples from these same lots. END NOTE. SFDA officials told Baxter privately at the Cherry Hill facility that they could not "get to" Baxter through the U.S. but they have total authority in China.

¶5. (SBU) Baxter employees said that through some miscommunication, the SFDA team also came away from the meeting at Cherry Hill with the mistaken impression that records related to the incident had been destroyed (as reported by the Chinese side). Baxter tried to provide related documents to SFDA and was told to use official channels in all future contact with the government agency.

¶6. (SBU) Since then, on April 22 and April 29, the company tried to follow up with SFDA to provide the requested additional paperwork (redacted medical records of those patients suffering from the adverse allergic drug-reactions). These documents were sent by Baxter to SFDA via courier, and the first shipment seemed to have been received; the second shipment was refused and returned. Baxter also indicated that it asked SFDA for a specific address to ship the requested samples, but SFDA has not answered Baxter on where the samples should be sent. To date, no production samples have been shared by Baxter due to this lack of a specific recipient and address provided by SFDA. In the subject meeting, Baxter indicated its preference to provide the sample to the FDA, which might retain a portion as a control sample and then have FDA ship it directly to SFDA.

¶7. (SBU) Baxter believes SFDA working level authorities are taking out their frustrations over miscommunication and the visit to the Cherry Hill plant. Those officials who visited the Cherry Hill facility are affiliated with SFDA's National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) and were responsible for performing the tests on heparin samples to determine whether there was, or was not contaminant present in the samples tested in China.

¶8. (SBU) Baxter requested in the subject meeting whether the Health and Human Services Attache could personally deliver requested production samples to the appropriate SFDA office. The HHS Attache agreed to check with FDA about this, and expressed concern over the chain of custody in doing so, but promised to get back to Baxter. Baxter hopes to maintain constructive ties with SFDA authorities on both sides and to get through the current impasse.

DRUG SAFETY LOOPHOLES STILL APPARENT

¶9. (SBU) Under current regulations, pharmaceutical companies in China that manufacture only for the export market are not subject to the authorities and regulations of SFDA, since the product would not be used in the domestic China market. Moreover, certain pharmaceutical ingredients that are declared or classified as chemicals are not subject to SFDA regulations and authorities either, even if their only real applications are in pharmaceuticals. This issue, regulation of active pharmaceutical ingredients (API), and the apparent black-hole this represents in the normally tightly-controlled regulatory environment for pharmaceuticals, was discussed during the negotiations that occurred between

SFDA and HHS/FDA last fall leading up to the signing of the Memorandum of Agreement for Drug and Medical Product Safety at December 2007's SED. Vice Premier Wu Yi in her closing remarks at the December 2007 JCCT even noted this lack of control and regulation of APIs as a concern that needed to be addressed by China and indicating that the State Council would likely begin to address this in the coming year.

A SHIELDING STRATEGY AT SFDA?

¶10. (SBU) COMMENT: The heparin incident and the aforementioned loopholes have created a liability and public opinion problem for which the SFDA is reluctant to take responsibility. In its press statements, the SFDA has continually indicated that the heparin-issue is an American problem, as the plant in question (Changzhou SPL) is an American joint-venture manufacturing its heparin sodium U.S.P. solely for export to its parent American firm, for use by Baxter. SFDA has reiterated that the China-based plant was neither under SFDA responsibility nor regulation. The aftermath of the 2007 food and product scare, as well as the internal shakeup of SFDA in 2006-7 and the execution of the SFDA Commissioner last year have weakened the SFDA to the point that it has little political capital to expend. Further deterioration of the SFDA's credibility would have a major impact for consumer confidence in

China as a safe source of pharmaceuticals. It appears possible that concerned officials may try to shift or spread blame in order to shield the agency from further criticism and in order to protect China's image among consumers. A recent decision to bring SFDA back under the Ministry of Health (MOH) is part of a government-wide plan to streamline and coordinate authorities while intensifying regulation of drug products. This change, an outcome of the March 2007 National Party Congress (NPC), will likely enhance SFDA's ability to enforce drug regulations and to develop a stronger regulatory framework with the MOH. END COMMENT.

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